www.GOP.gov
LEGISLATIVE DIGEST
HOUSE REPUBLICAN CONFERENCE
CHAIRMAN ADAM PUTNAM WASHINGTON D.C. 226-2302

H.R. 4 Medicare Prescription Drug Price Negotiation Act of 2007

Floor Situation

Title V (Section 506) of H.Res 6 made H.R. 4 in order under a closed rule with three hours of debate equally divided with one motion to recommit. This legislation has not been considered during the 110th Congress by any committee or the Committee on Rules.

Summary

H.R. 4 would amend Medicare Part D to require the Secretary of Health and Human Services (HHS) to negotiate covered Part D drug prices on behalf of Medicare beneficiaries. Specifically, the legislation would:

- Require the Secretary of HHS to negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations for covered Part D drugs for Part D eligible individuals who are enrolled under a prescription drug plan or under an Medicare Advantage Prescription Drug plan (MA-PD).

  **Note: There are negotiations under the current Medicare Part D program without government intervention. The price of drugs and pharmacy services is determined through negotiations by plan providers and drug makers. The outcomes of these negotiations affect plan bids and premiums. Part D enrollees' benefit from this free-market competition as the average price of premiums continues to decline from what was expected. See "How Part D Works" below.*

- Prevent the Secretary of HHS from constructing a particular prescription drug formulary.

  **Note: Banning a national formulary does not protect beneficiaries from other government access controls to prescription drugs. For instance, the Medicaid program has no national formulary, however, it employs various strategies such as a "preferred drugs list to limit access of medications." If beneficiaries want to receive a medication that is not on the preferred drug list, they must go through a lengthy and confusing authorization. See "Government Non-Interference Clause."*

- Permit PDPs and MA-PDs to obtain a discounted rate lower than the Secretary of HHS.

**Note: Under current law private PDPs and MA-PDs compete in a free-market environment in order to obtain more enrollees by offering the lowest rate.*

- Require the Secretary of HHS to submit a semi-annual report to Congress.
- Take effect January 1, 2008.

Background

On November 22, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (HR 1) passed the House, by a recorded vote of 220 - 215 (Roll No. 669), and on December 8, 2003, was signed into law by President Bush (PL 108-173). The Medicare Prescription Drug plan went into effect on January 1, 2006.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new prescription drug benefit under Medicare Part D. This prescription drug plan is a market-based approach where private insurers offer Medicare benefits and assume some of the risk for their enrollees.

Part D is designed to increase beneficiaries' access to prescription drugs by lowering the cost and providing more drug options.

Government Non-Interference Clause

In 2003, when the MMA passed, it included an element referred to as the "Government Non-Interference Clause." This clause prevents the federal government from intervening and attempting to negotiate drug prices. The purpose of the Government Non-Interference Clause is to ensure that various drug companies establish drug prices through competition in a free and open market.

H.R. 4 strikes the Government Non-Interference Clause and further mandates that the Federal government negotiate drug prices for Medicare Part D.

On January 10, 2007, the nonpartisan Congressional Budget Office (CBO) issued a letter to Chairman Dingell stating that removing the Government Non-Interference Clause "would have a negligible effect on federal spending" and would not be successful at lowering the cost of prescription drugs. According to CBO estimates, considerable savings are obtained by private plans because they will assume substantial financial risk, and therefore private plans will have strong incentives to negotiate price discounts, both to "control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements." Further, the Secretary of HHS would be "unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs under current law."

Government intervention can prevent access to the most advanced medicines. For instance, allowing the government to negotiate drug prices will limit the resources and the incentive for

drug company investment in research and development. More importantly, under price controls, patients are unlikely to have coverage for the most advanced medicines, which would directly affect many beneficiaries with severe medical conditions such as Alzheimer's disease, cancer, Multiple Sclerosis, or diabetes.

On March 9, 2000, President Clinton issued a press release supporting the Government Non-Interference Clause. In this release, President Clinton and Senate Democrats supported private sector negotiation of prescription drugs available through Medicare and agreed that the Federal government should be left out of the process. Specifically, the letter stated that "[d]iscounts should be achieved through competition, not regulation or price controls, and should mirror practices employed by private insurers in delivering prescription drugs. Private organizations should negotiate prices with drug manufacturers and handle the day-to-day administrative responsibilities of the benefit."

The Status of Medicare Part D Today

Since the implementation of Medicare Part D, data and analysis reveal a growth in the number of plans offered, an increasing number of enrollees, a low cost of prescription drugs, a decrease in premium prices, a lower impact of the coverage gap, and overall beneficiary satisfaction.

How Part D Works

The Medicare Part D prescription drug program is administered through the Centers for Medicare & Medicaid Services (CMS). CMS facilitates an open market amongst companies offering prescription drug plans (PDP), pharmacies, and Medicare beneficiaries who wish to enroll.

Plans Offered

Medicare Part D prescription drug coverage is provided through two different private plans, either stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDs)–such as Health Maintenance Organizations (HMOs) or Preferred Provider Organizations (PPOs). Different PDP and MA-PD plans are available in various parts of the country. CMS established 26 regions for Medicare Advantage Preferred Provider Organizations and 34 regions for prescription drug plans. Various plan providers across the country who intend to offer Medicare Part D submit bids to CMS for the cost of basic prescription drug benefits. CMS calculates the national average and, based on a percentage of that number, Medicare pays plans the same capitated, or flat dollar amount, per enrollee, adjusted for the risk of the individual enrollee. As previously mentioned, the price of drugs and pharmacy services is determined through negotiations by plan providers and drug makers. The outcomes of these negotiations influence plan bids and premiums. Under this free-market system, Part D enrollees are benefiting from the decline in the average price of premiums due to competition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) outlined four levels for a standard Part D drug benefit:

- Deductible: The beneficiary is subject to a $250 deductible to be paid out of pocket;

- Partial Coverage: Following the deductible the beneficiary is responsible for 25 percent of covered drug expenses with the provider funding the remaining 75 percent -up to an initial limit of $2,250;
- Coverage Gap: Between the initial coverage limit ($2,250) and the threshold of $3, 600 there is a coverage gap ("the donut hole") where the beneficiary is responsible for 100 percent of their drug costs;
- Catastrophic Coverage: Beyond the $3,600 cap, individuals are responsible for whichever is a greater - either a 5 percent coinsurance or co-pays of $2 for generic drugs and $5 for brand name drugs.

The guidelines established in MMA do not specifically define what a provider must include in Part D benefits. This approach is advantageous to organizations offering Part D, providing the flexibility to design and administer various kinds of prescription drug plans. Likewise, Part D favors beneficiaries with the freedom to select a plan that is best for them.

Enrollment

Enrollment in a Medicare Part D plan is voluntary. Individuals may chose to either participate in a Medicare Part D plan or obtain credible coverage from an alternative source. Credible coverage alternatives to Part D include employers or other government programs, such as the Department of Veterans Affairs (VA), and credible coverage must provide equal or greater coverage than Part D plans. Beneficiaries are provided an opportunity each year during an open enrollment period to enroll or change their enrollment in a drug plan.

Plans Available

Since the establishment of Medicare Part D, there have been 1,429 prescription drug plans (PDP) and 1,314 Medicare Advantage prescription drug plans (MA-PD) available throughout the regions nationwide (excluding the territories).[1]

- Beneficiaries in most states have a choice of at least 40 stand-alone PDPs and one or more MA-PD plans from which to select.[2]

- Only five states offer less than 40 plans.

- Two states' beneficiaries can chose between over 50 different plans.[3]

- Approximately 90% of the 43 million individuals eligible for Medicare Part D are currently enrolled in a credible prescription drug plan.

Prescription Drug Costs

[1] The Kaiser Family Foundation. *The Medicare Prescription Drug Benefit*. 6/2006. http://www.kff.org/medicare/upload/7044-04.pdf

[2] *Ibid.*

[3] *Ibid*.

Since the implementation of Medicare Part D, the Centers for Medicare & Medicaid Services (CMS) has been conducting analysis regarding the plan's effect on drug prices, and have found positive results. There are several areas where Part D is providing savings on prescription drugs, including a lower rate of Part D price increases as compared to average wholesale prices, price discounts, and the access to lower-cost alternatives.[4]

CMS' analysis reveals that the average wholesale price (AWP) of prescription drugs has increased at a greater rate than the price of Medicare Part D drugs.

- AWP is the base price at which pharmacists purchase prescription drugs, and an increase in AWP is typically accompanied by a comparable increase in the consumer drug price.

- Because Part D prices are increasing at a lower rate than AWP, those who are enrolled in Medicare experience a lower percentage increase in their drug prices than those who receive other prescription drug coverage.

- This is due to free market negotiation of price discounts by plans that offer Medicare Part D.

CMS' study also found continued drug savings to beneficiaries at their local pharmacies due to the negotiated discounts that Medicare drug plans are obtaining from pharmaceutical manufacturers.

According to CMS, beneficiaries are using information provided by Medicare and saving money on their drugs by utilizing lower cost alternatives. Medicare publishes information regarding the broad range of plans offered; enabling beneficiaries to find the plan that will save them money, while still meeting their prescription drug needs.[5]

<u>Enrollment</u>

There are 43 million Medicare beneficiaries. As of June 11, 2006 the Department of Health and Human Services (HHS) reported that since Medicare Part D went into affect 22.5 million beneficiaries have enrolled.[6] Out of the remaining Medicare Part D population 10.4 million receive prescription drug coverage from their employer and HHS estimates that another 5.4 million individuals have credible coverage from an alternative source, such as the Department of Veterans Affairs.[7] In January 2007 CMS reported the number of new online enrollees in the Medicare Part D program to be 316,000 between November 15th and December 31st, 2006. This data is preliminary because it includes only the number of online enrollees, so the number is expected to rise. However, including the data for those who enrolled in the initial open period,

---

[4] Centers for Medicare & Medicaid Services. "Large Negotiated Price Discounts Continue in Medicare Part D" 6/20/2006. http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1885

[5] *Ibid.*

[6] The Kaiser Family Foundation. *The Medicare Prescription Drug Benefit*. 6/2006. http://www.kff.org/medicare/upload/7044-04.pdf

[7] *Ibid.*

as well as those who have enrolled online since November 15th, there are 39 million –or 90 percent- of the 43 million individuals eligible for Medicare Part D who are currently enrolled in a credible prescription drug plan.

Premium Costs

Medicare beneficiaries are also saving on prescription drug plans with their monthly premium.

- The average premium in 2006 for the basic Medicare drug benefit is around $24. This is a significant decrease from original estimates after drug bidding of $32 per month on average – a difference of 25 percent.[8]

- In 2007, CMS expects the average cost of the Medicare prescription drug plans will remain stable or decline, with the average premium paid by beneficiaries to remain around $24 or less.[9]

- According to CMS the lowest premium for basic plans for 2007 ranges from approximately $10 in the Upper Midwest; $11 in TX, and in all cases under $20 in 2007, as in 2006. Beneficiaries had access to between 27 and 41 plan options with no deductibles in 2007.

The Coverage Gap

The coverage gap or "donut hole" refers to the period when spending levels on prescription drugs are between $2,400 and $3,850 in 2007, in which the beneficiary is responsible for all prescription drug expenses. Originally this was one of the most contested elements of Medicare Part D, because many argue that the donut hole leaves beneficiaries vulnerable to high out of pocket costs. However, analysis over the last year has revealed that the coverage gap is only having a minor effect on the Medicare Part D population.

- There are 22.7 million individuals enrolled in Medicare Part D:
    - 10 million beneficiaries have low incomes qualifying them for coverage without a gap;
    - 2.4 million have enhanced plans that provide partial coverage in the gap; and
    - 7 million are not subject to the donut hole because they have a spending level below the $2,250 threshold.[10]

[8] Centers for Medicare & Medicaid Services . NATIONAL BENCHMARK SHOWS IMPACT OF STRONG COMPETITIVE BIDDING AND SMART BENEFICIARY CHOICES. 8/15/2006 http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1945

[9] Centers for Medicare & Medicaid Services . NATIONAL BENCHMARK SHOWS IMPACT OF STRONG COMPETITIVE BIDDING AND SMART BENEFICIARY CHOICES. 8/15/2006 http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1945

[10] PriceWaterhouseCooper. "Significance of the Coverage Gap Under Medicare Part D" 6/2006, http://www.hlc.org/HLC_Coverage_Gap_Research_Report_FINAL.pdf

- Out of the nearly 23 million individuals enrolled in Medicare Part D only 8 percent (3.4 million) will be fully responsible for expenditures in the coverage gap.[11]

According to testimony given by CMS Administrator Mark McClellan and data collected through beneficiary satisfaction surveys, 84 percent of seniors enrolled in the Medicare prescription drug program are satisfied with their coverage and 52 percent say they are enjoying significant cost savings.[12]

The Department of Veterans Affairs (VA) as a Healthcare Model

Proposals calling for government negotiated drug prices, such as HR 4, often compare the VA healthcare system as a model for how government intervention can improve health benefits. However, this would be comparing "apples to oranges."

Authorized by the Veterans Health Care Act of 1992 (PL 102-585), the Secretary of Veterans Affairs is permitted to negotiate prices for covered drugs. The VA is a direct provider of medical services that owns and operates its own medical facilities, including: hospitals, out-patient clinics, and pharmacies. Doctors and medical providers are VA employees. A veteran under the VA's health care may seek care only from a closed network of approved hospitals and doctors.

The VA has 170 pharmacies at hospitals and clinics across the country which can provide over the counter services to veterans. 80 percent of prescriptions filled by the VA are filled through their mail-order system.

There are several characteristics that set the VA population apart from the rest of the Medicare Part D population:

- The VA model relies on a small homogeneous model where there is a national formulary delivering drugs to standard VA-owned hospitals and pharmacies;
- There are only 3.8 million people enrolled in the VA health service, while 33 million individuals are enrolled in Part D

The VA formulary is very different from formularies offered by Medicare prescription drug plans:

- The VA formulary requires access to 31 classes of prescription drugs, while Medicare Part D requires that beneficiaries have access to drugs in 209 therapeutic classes.

---

[11] PriceWaterhouseCooper. "Significance of the Coverage Gap Under Medicare Part D" 6/2006, http://www.hlc.org/HLC_Coverage_Gap_Research_Report_FINAL.pdf

[12] McClellan, Mark, MD, PHD, CMS Administrator. Testimony Before the House Committee on Ways and Means, Subcommittee on Health. 5/3/2006. http://waysandmeans.house.gov/hearings.asp?formmode=view&id=4909

- Only 38% of the drugs approved by the FDA in the 1990s and 19% of the drugs approved since 2000 are on the VA national formulary.[13]
- Approximately 40 percent of the 3.8 million Medicare beneficiaries enrolled in the VA for health benefits have also signed up for Medicare Part D coverage.

**Note: The VA cost estimates are not as low as they appear, because the do not include pharmacy and administrative services expenditures, which are included in Part D budget estimates.*

Additional Information

CMS Homepage

CMS Press Release on H.R. 4

VA Homepage

CBO Letter to Chairman Dingell

President Clinton Press Release

Staff Contact
For questions or further information contact Corrine Williams and Chris Vieson at (202) 226-2302.

[13] Turner, Grace-Marie. "The New Medicare: A Healthy Choice." Galen Institute. 6/28/2006/ http://www.galen.org/medicare.asp?docID=905